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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,179	03/22/2001	Tae-Wan Kim	0609.4910002/JAG/JUK	8573

24961 7590 09/23/2002

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/23/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,179

Applicant(s)

KIM ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION**1. Formal Matters**

A. Claim 1-41 are pending in this application and were subject to restriction in Paper No. 7 dated 1/7/02. In Paper No. 9, filed 7/8/02, Applicants elected Group I, claims 1-16 and 41, without traverse. However, upon further consideration, the claims of Group I are subject to further restriction. Therefore, all pending claims, 1-41, will be re-restricted.

2. Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 in part, 4 and 7-8 in part, drawn to a method of identifying agents to treat a neurodegenerative disease by assaying for CCE in cells expressing a presenilin mutation, classified in class 435, subclass 7.2.
- II. Claims 1-3 in part, 5 and 7-8 in part, drawn to a method of identifying agents to treat a neurodegenerative disease by assaying for CCE in cells expressing an APP mutant, classified in class 435, subclass 7.2.
- III. Claims 1-3 in part, 6 and 7-8 in part, drawn to a method of identifying agents to treat a neurodegenerative disease by assaying for CCE in cells expressing an APOE mutant, classified in class 435, subclass 7.2.
- IV. Claims 1 in part, 9 and 41, drawn to a method of identifying agents to treat a neurodegenerative disease by assaying for CCE in the presence of overexpressed TRP, classified in class 435, subclass 7.2.
- V. Claims 10 and 11 in part, 12 and 15, drawn to a method of identifying inhibiting CCE-linked gamma secretase activity in cells expressing a presenilin mutation, classified in class 435, subclass 7.2.
- VI. Claims 10 and 11 in part and 13, drawn to a method of identifying inhibiting CCE-linked gamma secretase activity in cells expressing an APP mutant, classified in class 435, subclass 7.2.
- VII. Claims 10 and 11 in part and 14, drawn to a method of identifying inhibiting CCE-linked gamma secretase activity in cells expressing an APOE mutant, classified in class 435, subclass 7.2.

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- VII. Claims 10 in part and 16, drawn to a method of identifying inhibiting CCE-linked gamma secretase activity in the presence of overexpressed TRP, classified in class 435, subclass 7.2.
- VIII. Claims 17-22 and 34-36, drawn to a method of treating neurodegenerative diseases in a subject by potentiating CCE, classified in class 514, subclass 2.
- IX. Claim 23, drawn to a method of identifying a TRP which increases CCE, classified in class 435, subclass 7.1.
- X. Claim 24, drawn to a method of identifying inhibitors of CCE using SKF96365, classified in class 435, subclass 7.1.
- XI. Claims 25-26 in part and 27, drawn to a method of identifying modulators of amyloid β peptide A β 42 wherein the cells comprise a mutant presenilin, classified in class 435, subclass 7.1.
- XII. Claims 25-26 in part and 28, drawn to a method of identifying modulators of amyloid β peptide A β 42 wherein the cells comprise a mutant APP, classified in class 435, subclass 7.1.
- XIII. Claims 29 and 30, drawn to a method of identifying modulators of amyloid β peptide A β 42 and those useful in the treatment of neurodegenerative disease by assaying for TRP, classified in class 435, subclass 7.1.
- XIV. Claims 31-33 in part and 37, drawn to a method of reducing amyloid β peptide A β 42 by administering an agent that potentiates CCE, including a TRP agonist, classified in class 435, subclass 7.1.
- XV. Claims 31-33 in part, 38 and 40, drawn to a method of reducing amyloid β peptide A β 42 by administering an agent that potentiates CCE, including regulating TRP expression, classified in class 435, subclass 7.1.
- XVI. Claims 31-33 in part and 39, drawn to a method of reducing amyloid β peptide A β 42 by administering an agent that potentiates CCE, including regulation of TRP maturation, classified in class 435, subclass 7.1.

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B. The inventions are distinct, each from each other because of the following reasons:

Inventions I-XVI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

C. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 19, 2002

